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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/827,371	04/06/2001	David Hung	05284.00085	3897

22907 7590 02/28/2003

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EXAMINER

FLOOD, MICHELE C

ART UNIT	PAPER NUMBER
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1654

DATE MAILED: 02/28/2003

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/827,371

Applicant(s)
Hung

Examiner
Michele Flood

Art Unit
1654



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on Feb 11, 2003

2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 1 and 6-33 is/are pending in the application.

4a) Of the above, claim(s) 12-21 and 28-33 is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☐ Claim(s) _____ is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☒ Claims 1, 6-11, and 22-27 are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. _____.

3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)

4) ☐ Interview Summary (PTO-413) Paper No(s). _____

2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-949)

5) ☐ Notice of Informal Patent Application (PTO-152)

3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____

6) ☐ Other:

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DETAILED ACTION

Acknowledgment is made of the receipt and entry of the amendment made after Final in Paper No. 12. Upon further consideration, the finality of the Office action of Paper No. 11 (dated November 14, 2002) has been withdrawn, and a restriction requirement has been deemed necessary as set forth below.

Election/Restriction

Applicant traverses the election by original presentation of submitted Claims 16-33, as set forth in the previous Office action. Claims 22-27 are rejoined to Claims 1 and 6-11, as the claims were inadvertently omitted for examination on the merits. Although Applicant argues that an "additional process step in a method does not *per se* render a method a separate patentable invention", the Office maintains that submitted Claims 16-21 and 28-33 are directed to an independent or distinct invention from the invention originally claimed. For instance, the invention of Claims 1, 6-11 and 22-27 is directed to a method for preparing for intraductal retrieval of fluid, cells and/or other material from a breast duct of a patient comprising administering intraductally an agent that increases retrievable secreted ductal fluid from a breast duct wherein the agent is selected from a recited Markush group, whereas the invention of Claims 16-21 and 28-33 is directed to a method for preparing for intraductal retrieval of fluid, cells and/or other material from a breast duct of a patient comprising administering intraductally to the patient an agent that increases retrievable secreted ductal fluid from a breast wherein the

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agent is selected from a recited Markush group; and, accessing the breast duct with a device and withdrawing a portion of the increased retrievable ductal fluid into the device. The invention of Claims 16-21 and 28-33 requires an additional process step not required in the originally elected invention; and, thus the invention is clearly beyond the limitations of a method for preparing for intraductal retrieval of fluid, cells and/or other material from a breast duct of a patient because the additional step of Claims 16-21 and 28-33 encompasses accessing the breast duct with a device and withdrawing (collecting) a portion of a ductal fluid into the device.

Since applicant received an action on the merits for the originally presented invention, the invention remains constructively elected by original presentation for prosecution on the merits. Accordingly, claims 16-21 and 28-33 remain withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claims 1, 6-11 and 22-27 are under examination.

1. This application contains claims directed to the following patentably distinct species of the claimed invention: the distinct and numerous ingredients of Claim 1, which represent numerous distinct compounds that have nothing in common: for example, a hypotonic solution vs. a buffered solution vs. a nonabsorbable biocompatible solution vs. a protein vs. a colloid vs. a sugar vs. a polymer vs. polyethylene glycol vs. maltodextrin vs. dextran vs. hydroxyethyl starch vs. an antibody vs. a binding protein vs. albumin vs. a hormone vs. an extract from a natural herb vs. a growth factor vs. a muscle relaxant vs. a ductal orifice dilator.

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Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, Claims 8-11 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

2. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michele Flood whose telephone number is (703) 308-9432. The examiner can normally be reached on Monday through Friday from 7:15 am to 3:45 pm. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196 or the Supervisory Patent Examiner, Brenda Brumback whose telephone number is (703) 306-3220.

Michele C. Flood.

MCF

February 27, 2003